

EVALUATION OF A COMBINATION OF A UNANI PHARMACOPEAL PREPARATION (ITRIFAL USTUKHUDOOS) WITH CLOVES (QARANFAL) IN ALLERGIC RHINITIS – A PRELIMINARY CLINICAL STUDY.

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ABSTRACT : Allergic Rhinitis is typically characterized by sneezing, rhinorrhoea, nasal obstruction, nasal, conjunctival & pharyngeal itching and lacrimation all occurring in a temporal relation to allergen exposure. The peak incidence of this disease occurs in childhood and adolescence, with most of the cases belonging to the atopic category.

There is a high incidence of patients of allergic rhinitis attending the outdoor sections of Ajmal Khan Tibbiya College Hospital. Many of them are dissatisfied with conventional anti-histaminic drugs. An open study was carried out on 20 such patients aged between 15 to 50 years to evaluate the clinical efficacy of a unani pharmacopeal preparation [Itrifal Ustukhudoos] added with cloves [qaranfal]. Preliminary clinical study showed promising results. The study is into the next phase in which a comparative double-blind trial is being conducted with this combination and Allegra (Fexofenadine hydrochloride).

INTRODUCTION

Allergic rhinitis is an inflammatory condition of the nose characterized by sneezing, rhinorrhoea and nasal obstruction. Often it may be associated with conjunctival and pharyngeal itching, lacrimation and sinusitis. The disease has a widespread incidence. Although commonly seasonal, it can be perennial in an environment of chronic exposure. Majority of the cases belong to the childhood & adolescent age groups^{3,4,6}. There is a detailed and ample description of rhinitis as ‘zukaam’ in the Unani literature. This has been described as a condition in which the catarrhal matter flows towards the nasal cavity. Hippocrates has described zukaam as the ‘nazal’ or catarrhal inflammation of the nasal mucosa^{5,7}. Yet there is no specific description of the allergic variety in the Unani literature.

The pathophysiology of this disease is the immediate hypersensitivity reaction occurring in the nasal mucosa on exposure to variety of allergens. Most of the case have an atopic tendency to various collateral allergies like eczematous dermatitis, urticaria and/or asthma. Very often, there is a family history of such disease also^{2,4}.

The first step in the diagnosis of this diseases involves its differentiation into seasonal & perennial varieties. The diagnosis depends largely on the an accurate history of occurrence coincident with the pollination and/or other identifiable allergens like dust mite, animal dander, etc.^{3,4}.

Avoidance of exposure to the offending allergen is the most effective means of controlling allergic diseases. The treatment given comprises of various drug classes like antihistamines, sympathomimetics, topical steroids & mast cell stabilizers. Immunotherapy, also called as hyposensitisation is also used if conservative therapy fails^{2,4}.

In spite of the better understanding of hypersensitivity reaction and their mediators, and newer specific classes of drugs (like mast cell stabilizers), the morbidity from allergic rhinitis is not much influenced. This study was carried out, keeping this and a few other points, described below, in mind.

MATERIALS AND METHODS

The basic objective of this study was to evaluate the therapeutic efficacy of unani pharmacopeal preparation *Itrifal Ustukhudoos* plus *Qaranfal* (*Eugenia coryophyllata*) in allergic rhinitis. Some of the motivating factors behind this study were as follows:

- ❖ A high incidence of patients of this disease in our hospital.
- ❖ Dissatisfaction of the patients with the conventional antihistaminics.
- ❖ Literature supporting the use of *Itrifal Ustukhudoos* in *nazla* and *zukaam*, and cloves in various allergies.^{5,7}

The location of this study was the unani outdoor sections of Ajmal Khan Tibbiya College Hospital. Twenty patients of this disease were selected for this study on the basis of following criteria.

Inclusion Criteria:

- ❖ Presence of symptoms like sneezing, nasal obstruction and rhinorrhoea.

- ❖ Occurrence of these symptoms in sudden attacks and episodes.
- ❖ Positive family history of at least any one of the three diseases- allergic rhinitis, allergic dermatitis or bronchial asthma.
- ❖ Eosinophilic count > 09/cu.mm.

Exclusion Criteria:

- ❖ Subjects aged less than 15 years and more than 50 years.
- ❖ Patients suffering from concomitant diseases like chronic bronchitis, pulmonary tuberculosis, vasomotor rhinitis and nasal polyposis.

The composition of *Itrifal Ustukhudoos* is shown in Table No. A¹². Patients were administered 6 gms. of *Itrifal Ustukhudoos* (prepared by Dawakhana Tibbiya College, AMU Aligarh) plus 2 powdered cloves twice a day for four consecutive weeks. Patients were also directed to avoid exposure to any identifiable aggravating factors like house dust and contact with pets.

OBSERVATION AND RESULTS

The clinical and haematological assessment of all the cases was made at weekly intervals. The diagnosis of this disease depends mainly on accurate history, yet there are many investigations describe in textbooks. Some of them are examination of nasal secretions, Serum IgE estimation and skin hypersensitivity tests. Due to limited resources we had to rely on clinical features, physical examination and eosinophilic count.

DISCUSSION AND CONCLUSION

The baseline observations tabulated in Tables A & B indicate that 75% of the patients belonged to the age-group below 40 years. It was also observed that all the patients had the positive family history of allergic disorders.

These findings are consistent with the descriptions given in the standard unani and modern medical textbooks^{2,3,4,5,6,7}.

In our study, the hallmarks of the disease viz., sneezing, rhinorrhoea and nasal obstruction were present in all the 20 cases. There was an overall improvement of 50-80% in these features. This effect is most likely because of the clearance on nasal passage (of phlegmatic secretions) by the effect of *halela*, *balela senna* and *turbud*. Chebulinic and Chebulagic acids present in *halela* and *balela*, and aloe-emodin, cathartin & sennosides present in *senna* are the constituents which may have produced this effect^{9,10}. Linalyl acetate present in *ustukhudoos* is also an active constituent. That's why *ustukhudoos* is called as "broom of the brain"^{8,11}.

Similarly 18 patients suffered from itching of nasal cavity, pharynx and eyes. There was an

improvement of 72.23% which is most likely because of the clearance of phlegmatic matter. An improvement of 44.45% observed in nasal mucosal redness is most likely consequent to the anti-inflammatory effect of bioflavonoid present in *kishmish* and *maveez*^{9,10}.

The mean eosinophil count which was 10.6 at the start of the study showed an improvement percentage of 30%. This effect can be attributed to β -caryophyllene and eugenol acetate present in *qarantal*¹.

It may thus be concluded from this study that out combination of drugs resulted in the significant improvement (Table-F) in the overall clinical picture of allergic rhinitis. This study was quite limited in the first phase; however, subsequent studies are underway with an increased sample size.

Table – A
Showing Constituents of *Itrifal Ustukhudoos*

S.No.	Constituents	Part Used	Proportion
1	Halaila Zard (<i>Terminalia chebula</i>)	Bark	2 Parts
2	Halaila Siyah (<i>Terminalia chebula</i>)	Bark	2 Parts
3	Balela (<i>Terminalia bellerica</i>)	Bark	2 Parts
4	Amla (<i>Emblica officinalis</i>)	Fruit	2 Parts
5	Ustukhudoos (<i>Lavendula stoechas</i>)	Whole Plant	3 Parts
6	Senna (<i>Cassia augustifolia</i>)	Leaves	2 Parts
7	Turbud Sufaid (<i>Ipomoea Turpethum</i>)	Root	2 Parts
8	Bisfayaj (<i>Polypodium vulgare</i>)	Root	2 Parts
9	Mastagi (<i>Pistachia lentiscum</i>)	Gum	2 Parts
10	Afternoon (<i>Cuscuta chinensis</i>)	Whole Plant	2 Parts
11	Kishmish (<i>Vitis vinifera</i>)	Fruit	2 Parts
12	Munaqa (<i>Vitis vinifera</i>)	Fruit	2 Parts
13	Shahad khalis (Pure Honey)	-	75 Parts

TABLE – B
Showing age & Sex distribution
Total patients = 20

Age			Sex			
Age Groups (in years)	No. of Cases	% age	Male		Female	
			No. of cases	% age	No. of cases	% age
16 – 21	7	35.00	4	57.14	3	42.85
22 – 27	3	15.00	3	100.00	0	0
28 – 33	3	15.00	2	66.67	1	33.33
34 – 39	2	10.00	1	50.00	1	50.00
40 – 45	5	25.00	2	40.00	3	60.00
Total	20	100.00	12	62.77	8	37.23

Table – C
Showing family history in the patients

Disease	No. of patients	% age
Bronchial Asthma	9	45.00
Allergic Dermatitis	6	30.00
Allergic Rhinitis	5	25.00
Total	20	100.00

Table – D
Showing effect of drug on incidence of symptoms & signs

S. N o.	Symptoms & Signs	Before Treatment (O Days)		During & After Treatment							
				7 Days		14 Days		21 Days		28 Days	
		No. of patients	% age	No. of patients	Improvement % age	No. of patients	Improvement % age	No. of patients	Improvement % age	No. of patients	Improvement % age
1	Rhinorrhoea	20	100.00	20	0.00	15	25.00	12	40.00	10	50.00
2	Nasal Obstr.	20	100.00	18	10.00	13	35.00	9	55.00	6	70.00
3	Sneezing	20	100.00	16	20.00	10	50.00	8	60.00	4	80.00
4	Pruritus of Nasal cavity & pharynx	18	90.00	14	22.23	12	33.33	9	50.00	5	72.23
				13	18.75	11	31.25	8	50.00	4	75.00
5	Lacrimation	16	80.00	18	0.00	16	11.11	13	27.78	10	44.45
6	Nasal Mucosal Redness	18	90.00								
7	Conjunctiveal Inflammation	10	50.00	8	20.00	6	40.00	5	50.00	2	80.00

Table – E
Showing the effect of Drug on Eosinophil Count

Before Tt.	During & after treatment							
(O Day)	7 Days		14 Days		21 Days		28 Days	
	Mean Eosino.Count	Improv. % age	Mean Eosino.Count	Improv. % age	Mean Eosino.Count	Improv. % age	Mean Eosino.Count	Improv. % age
10.60	9.8	7.55	9.4	11.32	8.2	22.64	7.0	30.00

Table – F
Showing the most likely constituents responsible for the improvement in the Clinical Picture

S. No.	CI. Features / BI. Picture	Improv. % age	Constituents Responsible (Most likely)
1	Rhinorrhoea	50.00	<i>Halela & Balela</i> – Chebulinic acid
2	Nasal Obstruction	80.00	Chebulaginic acid
3	Sneezing	70.00	<i>Senna</i> – Aloe-emodin, cathartin, sennosides <i>Ustukhdoos</i> – Linalyl acetate
4	Nasal mucosal redness	44.45	Kishmish } Bioflavonoids (Anti-inflammatory effect) Munaqqa }
5	Increased Eosinophil Count	30.00	Qaranfal – β -caryophyllene, Eugenol & Eugenol acetate (anti-allergic effect)

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